UNITED STATES CONTINUATION-IN-PART PATENT APPLICATION

ENTITLED:

BODY FLUID COLLECTION APPARATUS

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By: Michelle A. Phinney

March 25, 2004
Date

BODY FLUID COLLECTION APPARATUS

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application Serial No. 10/154,512 filed May 24, 2002, the entire contents of which is hereby incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure generally relates to fluid collection apparatus, and more particularly, to an apparatus that facilitates fluid collection from an umbilical cord while preventing hazardous exposure to blood and body fluids collected.

2. Background of the Related Art

Body fluids, such as blood, urine, etc., can be collected during various medical procedures for analysis. For example, fluid and blood samples are typically collected from an umbilical cord of a newborn infant to ascertain blood type and Rh factor. Collection of umbilical cord blood is also beneficial due to its considerable curative value, e.g., use in bone marrow replacement procedures for treatment of cancer and immuno-deficiency disorders. Further, fetal blood has important commercial and therapeutic use in medical fields, such as, tissue culture, stem cell collection, pharmacology and biological research.

Several methods for umbilical cord blood sampling are known. One method includes holding a severed free end of an umbilical cord, still attached to a placenta, over a test tube or

container. Blood is drained from the placenta into the test tube or container by milking the umbilical cord. A typical sample requires about 5cc. This procedure has several disadvantages in that it is awkward to perform, difficult to control the sterility of the collected cord blood and may hazardously expose medical personnel to cord blood due to splattering, etc.

In another method, blood is drawn from the umbilical cord vein via a large gauge needle and syringe. This procedure is also awkward to perform and may hazardously expose medical personnel to potential needle sticks. More recently, an umbilical cord segment is clamped on two ends and moved to a collection device or container where the cord blood is drained by removing the clamps from either or both ends. Ultimately, the cord blood must be transferred to a storage container, such as a test tube, to prevent contamination of the blood and minimize hazardous exposure to health care workers. These funnel type collection devices require larger apertures that interface with non-standard wide-mouthed test tubes because they rely on gravity to cause the blood to flow. Other cord blood collection devices include large containers to hold the entire cord segment. The containers are sealed so that vacuum pressure can be used to cause blood to flow through a smaller aperture or needle. Needle type interfaces, however, must include shielding to protect medical personnel. The necessary shielding adds more bulk to the collection device.

The above devices disadvantageously expose medical personnel to accidental needle sticks and potentially hazardous body fluids. Needlesticks can, for example, occur during manipulation of a collection device including, assembly, dis-assembly or insertion into a blood vessel of the umbilical cord. Hazards such as, for example, needlesticks, splattering, etc. can present dangerous exposure to fluids contaminated with bacterial diseases, and potentially fatal viral infections such as AIDS, Hepatitis B and C, etc.

Attempts have been made to overcome the disadvantages of the prior art and prevent hazardous exposure to blood and body fluids. Some designs employ a needle hood for a needle container which sealingly engages an evacuated tube. See, e.g., U.S. Patent Nos. 5,915,384 and 5,342,328. Designs of this type, however, still involve the use of a container with a needle and may not adequately prevent hazardous exposure to blood and body fluids. Still other designs employ complicated valve connections between a container and a syringe for receiving collected

cord blood. These prior designs, however, may not safely transfer fluid due to their complexity and number of parts. Complex structure can result in high manufacturing costs. Further, these configurations are not easily adapted to existing medical components.

Consequently, there remains a need to provide a more satisfactory solution for fluid collection apparatus by overcoming the disadvantages and drawbacks of the prior art. Therefore, it would be desirable to provide a fluid collection apparatus for collection of umbilical cord fluid which prevents hazardous exposure to blood and body fluids and is adaptable to existing medical components. Such a fluid collection apparatus should have reduced complexity to increase reliability and improve fluid collection. It would be highly desirable for the fluid collection apparatus to employ luer connections thereby minimizing the potential for inadvertent needle stick.

SUMMARY

Accordingly, the present disclosure addresses a need for a fluid collection apparatus which protects practitioners, supporting medical personnel and patients from hazardous exposure during umbilical cord fluid collection. The present disclosure resolves related disadvantages and drawbacks experienced in the prior art. More specifically, the apparatus and method of the present disclosure constitute an important advance in the art of fluid collection by providing an apparatus with reduced complexity and fewer needle interfaces. This structure advantageously improves safety and reliability while lowering manufacturing cost. Moreover, the apparatus does not require needle shields, etc. thereby reducing bulk. Desirably, the fluid collection apparatus employs luer connectors to avoid needle use and increase safety.

In one particular embodiment, in accordance with the principles of the present disclosure, a fluid collection apparatus is provided. The fluid collection apparatus includes a housing configured for receipt of fluid and has a first surface which defines a needleless first mating portion. A holder has a first end and a second end configured to receive an evacuated tube. The first end defines a second mating portion on an outer surface thereof which is in fluid communication with the evacuated tube. The first mating portion sealingly engages the second mating portion to establish fluid communication therebetween.

The housing may have a cylindrical body portion configured and dimensioned to support at least a portion of an umbilical cord. The first surface of the housing can have a funnel configuration. The first mating portion and the second mating portion may alternatively include a male connector and a female connector. Desirably, the first mating portion engages the second mating portion in a slip interference fit.

In another embodiment, the first mating portion has a locking surface that engages the second mating portion to lock the housing with the holder. The housing can be releasably locked with the holder. The locking surface may have a threaded portion that receives the second mating portion. In yet another embodiment, the first end of the holder includes a needle hub supporting a needle cannula in fluid communication with the second mating portion and extending away from the first mating portion. The needle cannula may engage the evacuated tube to establish fluid communication between the first mating portion and the evacuated tube.

In an alternate embodiment, an umbilical cord fluid collection apparatus includes a cylindrical housing defining a cavity for receipt of at least a portion of an umbilical cord. The housing has a funnel surface which defines a male luer connector. A holder has a first end and a second end configured to receive an evacuated tube. The first end defines a female luer connector on an outer surface thereof in fluid communication with an inner surface of the first end. The inner surface is in fluid communication with the evacuated tube. The male luer connector sealingly engages the female luer connector to establish fluid communication between the male luer connector and the evacuated tube. The configuration of the male luer connector of the housing advantageously facilitates adaptability to pre-existing holders having female luer connectors. The funnel surface may have a locking surface that engages the first end to lock the housing with the holder. The locking surface may be disposed about the male luer connector and includes a threaded portion that receives the first end of the holder. The inner surface of the first end can include a needle hub supporting a needle cannula in fluid communication with the female luer connector and extending away from the male luer connector. The needle cannula may engage the evacuated tube to establish fluid communication between the male luer connector and the evacuated tube.

A method for collecting umbilical cord fluid is provided including the steps of: providing a fluid collection apparatus, similar to those described, attaching a first mating portion to a second mating portion to form a non-puncturing seal therebetween; disposing umbilical cord fluid in a housing; inserting an evacuated tube with a holder to establish fluid communication between the second mating portion and the evacuated tube such that umbilical cord fluid is collected in the evacuated tube. The step of providing may include an inner surface of a first end of the holder having a needle cannula extending away from the first mating portion such that the step of inserting includes puncturing the evacuated tube with the needle cannula to establish fluid communication between the second mating portion and the evacuated tube.

Another particular embodiment of a fluid collection apparatus according to the present disclosure includes a support for standing the apparatus. As in the embodiments described above, a fluid collection apparatus includes a housing configured for receipt of fluid. The housing has a first surface which defines a needleless first mating portion. A holder having a first end and a second end is configured to receive an evacuated tube. The first end defines a second mating portion on an outer surface thereof which is in fluid communication with the evacuated tube. The first mating portion sealingly engages the second mating portion to establish fluid communication therebetween. A base disposed with the housing and being configured for support thereof.

In the particular embodiment, the base has a top opening adapted for receiving the housing. The base is adapted for standing on a surface and is configured to enclose the holder. The housing can have a flange portion extending radially therefrom that engages the base. In at least one embodiment, the base defines at least one rib which forms a step for supporting the housing. Similarly, the base can define a plurality of ribs, each forming a step for supporting the housing. The base can also includes a plurality of sidewall extensions separated by cutout portions. In an illustrative embodiment according to the present disclosure, the base is configured to enclose the housing when the housing is fitted to a holder with an evacuated tube installed in the holder.

Particular embodiments of apparatus according to the present disclosure also include a removable cap adapted to removably enclose an opening of the housing. The removable cap is

adapted to provide a fluid seal with said housing. An illustrative embodiment of such a cap includes a finger grip or similar gripping portion to aid in removal from the opening of the housing.

Another illustrative embodiment of the present disclosure includes a housing defining a cavity and being configured for receipt of fluid. A holder having a first end and a second end is configured to receive an evacuated tube. The first end includes a port that establishes fluid communication between the evacuated tube and the cavity of the housing. The port includes a needle cannula configured for disposal within the evacuated tube. The housing defines a well portion disposed adjacent the port of the holder. A bottom wall of the housing is sloped downward to define the well portion.

A removable cap can be adapted to removably enclose an opening of the housing and provide a fluid seal with the housing. The removable cap can also include a plurality of snap arms adapted for engaging the housing. A base can be disposed with the housing and configured for support thereof.

In still another embodiment of the present disclosure, a fluid collection apparatus includes a housing defining a first chamber. The housing is configured for receipt of fluid and a bottom wall of the housing has a sloped configuration. A holder defines a second chamber configured to receive a collection device having a port. The first chamber is in fluid communication with the second chamber via a passageway. A removable cap is adapted to removably enclose an opening of the housing and an opening of the holder.

In a particular embodiment, the removable cap includes a first cover that encloses the opening of the housing and a second cover that encloses the opening of the holder. The first cover and the second cover can be hingedly connected, for example. In another particular embodiment, the housing and the holder are monolithically formed.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the present disclosure are set forth with particularity in the appended claims. The present disclosure, as to its organization and manner of operation, together with further objectives and advantages may be understood by reference to the following description, taken in connection with the accompanying drawings, in which:

FIG. 1 is an enlarged side view, in part cross section, of one particular embodiment of a housing of a fluid collection apparatus, in accordance with the principles of the present disclosure;

FIG. 2 is a front plan view of the housing shown in FIG. 1;

FIG. 3 is a side perspective view of the housing shown in FIG. 1;

FIG. 4 is a side perspective view of the housing shown in FIG. 3 and a holder of the fluid collection apparatus;

FIG. 5 is a side perspective view of the housing and the holder shown in FIG. 4, assembled, and an evacuation tube of the fluid collection apparatus;

FIG. 6 is a side perspective view of the assembled fluid collection apparatus shown in FIG. 5 collecting fluid from an umbilical cord;

FIG. 7 is a side perspective view of the fluid collection apparatus shown in FIG. 5 upon collection of fluid;

FIG. 8 is a front cross sectional view a the fluid collection apparatus having a support according to a particular embodiment of the present disclosure;

FIG. 9 is a front cross sectional view a the fluid collection apparatus having a support according to an alternative embodiment of the present disclosure;

FIG. 10 is a front cross sectional view of a fluid apparatus according to the present disclosure having housing extensions forming a support according to an illustrative embodiment of the present disclosure;

FIG. 11A is a front cross sectional view of a cap adapted to cover a housing according to an embodiment of the present disclosure;

FIG. 11B is a partial front cross sectional view of an optional cap retention feature according to an illustrative embodiment of the present disclosure;

FIG. 12 is a front cross sectional view of a particular embodiment of a fluid collection apparatus according to the present disclosure having a cap with a tubular cavity disposed therein for receiving a fluid collection tube;

FIG. 13A is a cross sectional plan view of a multi-chamber fluid collection apparatus according to the present disclosure;

FIG. 13B is a front cross sectional view of a multi-chamber fluid collection apparatus according to the present disclosure;

FIG. 13C is a front cross sectional view of a multi-chamber fluid collection apparatus according to the present disclosure having a fluid collection holder installed therein; and

FIG. 13D is a front cross sectional view of a multi-chamber fluid collection apparatus according to the present disclosure having a cap installed therewith.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The exemplary embodiments of the fluid collection apparatus and methods of operation disclosed are discussed in terms of a fluid collecting device, and more particularly in terms of an umbilical cord blood collection apparatus that mates its constituent parts with a fluid collection holder that prevents hazardous exposure to blood and body fluids including, for example, inadvertent needle stick. It is contemplated that a housing of the fluid collection apparatus uses a needless mating connection to increase safety during use including storage, transport, fluid collection, subsequent thereto, etc. It is envisioned that the present disclosure, however, finds application to a wide variety of fluid collection procedures relating to analysis, sampling, diagnosis, treatment, etc. It is further envisioned that the present disclosure may be employed for collection of various body fluids including those relating to phlebotomy, digestive, intestinal, urinary, veterinary, etc. It is contemplated that the components of the fluid collection apparatus may be utilized with other medical application devices including phlebotomy devices, catheters,

catheter introducers, guide wire introducers, and those employed during procedures relating to spinal and epidural, biopsy, aphaeresis, dialysis, etc.

In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a practitioner, and the term "distal" refers to a portion that is further from the practitioner. As used herein, the term "subject" refers to a patient that has blood and/or fluid collected therefrom using a fluid collection apparatus. According to the present disclosure, the term practitioner refers to an individual performing fluid collection, installing, assembling or removing the fluid collection apparatus and may include support personnel.

The following discussion includes a description of the fluid collection apparatus, followed by a description of the method of operating the fluid collection apparatus in accordance with the present disclosure. Reference will now be made in detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGS. 1 and 2, there is illustrated a cylindrical housing 12 of an umbilical cord fluid collection apparatus 10 (FIG. 5), constructed in accordance with the principles of the present disclosure. Fluid collection apparatus 10 is advantageously configured to prevent hazardous exposure to blood and body fluids by providing a needleless sealing engagement between housing 12 and the components of fluid collection apparatus 10, as will be discussed. The design of fluid collection apparatus 10 provides improved reliability and reduces associated manufacturing costs.

Housing 12 is configured for receipt of a fluid, such as, for example, umbilical cord blood 13 (FIG. 6) and defines a cavity 14 for receipt of at least a portion of an umbilical cord 16 (FIG. 5). Cavity 14 is cylindrical, however, it is contemplated that the cavity may have other geometric configurations, such as, for example, rectangular, etc., according to the particular requirements of a medical application. Housing 12 has a first surface, such as, for example, a funnel 18. Funnel 18 is configured to direct cord fluid accumulation toward a central section thereof and consequently in position for collection into an evacuated tube 28 (FIG. 5). It is contemplated that gravity and/or a vacuum force from evacuated tube 28 cooperates with funnel

18 to draw fluid therethrough. It is envisioned that the first surface of housing 12 may have other orientations such as, for example, planar, etc.

Funnel 18 defines a first mating portion, such as, for example, a male luer connector 20 to facilitate a needless sealing engagement with a fluid collection holder 22, as shown in FIG. 4, and discussed below. Holder 22 has first end 24 that longitudinally extends to a second end 26. Holder 22 is substantially cylindrical and defines a tubular cavity 27. Second end 26 is configured to receive evacuated tube 28 for disposal within cavity 27. It is contemplated that cavity 27 may have various geometric cross-sections, such as, for example, circular, rectangular, etc. according to the requirements of a particular medical application.

First end 24 defines a second mating portion, such as, for example, a female luer connector 30 on outer surface 32 thereof. Female luer connector 30 engages male luer connector 20, as will be discussed, to form a needleless seal and facilitate transfer of cord blood 13 to evacuated tube 28. Female luer connector 30 is in fluid communication with an inner surface 34 of first end 24 which is in fluid communication with evacuated tube 28. In an alternate embodiment, the first mating portion may define a female luer connector, similar to connector 30, and the second mating portion may define a male luer connector, similar to connector 20.

Male luer connector 20 sealingly engages female luer connector 30 to establish fluid communication between male luer connector 20 and evacuated tube 28 thereby facilitating cord blood collection from umbilical cord 16 for appropriate sampling, analysis, etc. The sealing engagement of male luer connector 20 and female luer connector 30, in accordance with the principles of the present disclosure, advantageously prevents hazardous exposure to blood and body fluids by eliminating a needle seal and/or connection of housing 12 and the parts of fluid collection apparatus 10. This structure reduces the number of needles employed to facilitate cord blood collection thereby increasing safety to practitioners and subjects. Further, the configuration of male luer connector 20 of housing 12 facilitates adaptability to pre-existing holders having female luer connectors.

Fluid collection apparatus 10 is contemplated for use in the medical field of body fluid collection. More particularly, fluid collection apparatus 10 is envisioned to be a disposable device for collecting umbilical cord fluids and having, among other things, safety features that

include a needleless mating connection thereby preventing inadvertent needle sticking and hazardous exposure to blood and body fluids from practitioners and subjects, as well as uniform operation during a procedure. The above advantages, among others, realized from the present disclosure are attained through the disclosed fluid collection apparatus 10, as discussed herein. The features of the present disclosure advantageously facilitate safe collection of body fluids.

Fluid collection apparatus 10 is integrally assembled of its component parts. Alternatively, portions of fluid collection apparatus 10 can be monolithically formed and assembled therewith. Component parts of fluid collection apparatus 10 can be fabricated from a material suitable for medical applications, for example, polymerics or metals, such as stainless steel, depending on the particular medical application and/or preference of a practitioner. Semi-rigid and rigid polymerics are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. However, one skilled in the art will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

Housing 12 defines a flange 36 disposed adjacent and about an opening 38 of cavity 14. Flange 36 provides stability to housing 12 and facilitates manipulation thereof. It is contemplated that flange 36 may be variously disposed about housing 12. It is further contemplated that housing 12 may not include a flange. Cavity 14 is defined by walls 40 of housing 12. Cavity 14 has a reduced dimension and is appropriately sized to receive a portion of umbilical cord 16. Consequently, housing 12 is smaller and easier to manipulate. It is contemplated that housing 12 may be dimensioned to support an entire umbilical cord and/or various portions thereof. Housing 12 corresponds to the configuration of cavity 14, however, the outer surface of housing 12 may alternatively have geometric configurations, such as, for example, rectangular, elliptical, etc.

Funnel 18 tapers from walls 40 to male luer connector 20 to direct cord blood collected in cavity 14 to male luer connector 20. Varying degrees of funnel taper may be employed according to the requirements of a particular fluid collection application and/or preference of a practitioner.

Male luer connector 20 extends a sufficient length from funnel 18 to mate with female luer connector 30 of holder 22 in a slip interference fit. The slip interference fit includes a frictional engagement that maintains connectors 20, 30 in a sealing engagement. Female luer connector 30 correspondingly has a receiving depth at least a sufficient dimension to facilitate the slip interference fit with male luer connector 26. The slip interference fit provides a needleless sealing engagement that avoids the use of a needle and prevents hazardous exposure to cord blood.

Male luer connector has a tapered outer surface 44 that is configured to engage a tapered inner surface 46 of female luer connector 30. As outer surface 44 is caused to engage inner surface 46, sufficient friction is created therebetween to generate the slip interference fit and seal housing 12 with holder 22. The sealing engagement facilitates transfer of cord blood to evacuated tube 28 while avoiding needlesticks, splattering, etc. It is contemplated that surfaces 44, 46 may have variously tapered configurations, including non-tapered, depending on the sealing strength, etc. requirements of a particular medical application. It is further contemplated that male luer connector 20 may sealingly engage female luer connector 30 in various types of sealing engagements, such as, threaded friction fits, gasket, etc. sufficient to form a seal which facilitates fluid communication between housing 12 and evacuated tube 28.

Male luer connector 20 has an opening 42 that is appropriately dimensioned to facilitate passage of fluid therethrough and avoid blockage due to particles, etc. in the cord blood and fluid. It is envisioned that opening 42 may include screens, filters, etc. As shown in FIG. 3, a locking surface 48 extends from funnel 18 and is disposed circumferentially about male luer connector 20. Locking surface 48, including a threaded portion 50, extends an adequate length to receive a correspondingly threaded flange 52 of female luer connector 30. Flange 52 threads with portion 50 to releasably lock housing 12 with holder 22. Locking surface 48 may alternatively comprise circumferential notches disposed along male luer connector 20 which engage corresponding ridges of female luer connector 30 in a locked engagement. Other locking surfaces are contemplated such as, clips, catches, etc. It is contemplated that the locking surfaces may be permanent.

Referring to FIGS. 5 and 6, first end 24 of holder 22 has an inner surface 34. Inner surface 34 has a needle hub 54 supporting a needle cannula 56. Needle cannula 56 extends away from male luer connector 20 for appropriate puncture of a rubber stopper 58 of evacuated tube 28. Needle hub 54 and needle cannula 56 are in fluid communication with female luer connector 30. Needle cannula 56 engages rubber stopper 58 to establish fluid communication between male luer connector 20 and evacuated tube 28.

Needle cannula 56 punctures rubber stopper 58 such that the tip of needle cannula 56 is disposed in the evacuated space of tube 28. As needle cannula 56 communicates atmospheric pressure to the evacuated space of tube 28 via the fluid communication between housing 12 and evacuated tube 28, cord blood 13 disposed in funnel 18 is drawn through male luer connector 20, female luer connector 30, needle hub 54 and needle cannula 56 into tube 28. Cord blood 13 is drawn through this fluid flow path as pressure within tube 28 stabilizes to atmospheric pressure and the vacuum draws fluid therein. This fluid collection process is continued until tube 28 is filled or a desired amount of cord blood 13 is collected. Tube 28 is removed from needle cannula 56.

In use, fluid collection apparatus 10 and its component parts, similar to that described, is properly sterilized and otherwise prepared for storage, shipment and use. Referring to FIGS. 4-7, a practitioner prepares the necessary instruments, including fluid collection apparatus 10 for collecting blood from an umbilical cord of a newborn. It is envisioned that component parts of fluid collection apparatus 10 employed, such as, for example, holder 22, as described, may include pre-existing medical equipment for which housing 12 is easily adapted for use.

As shown in FIGS. 4 and 5, male luer connector 20 is mated to female luer connector 30 such that a non-puncturing sealing engagement is formed therebetween. Consequently, a seal is formed between housing 12 and holder 22. Flange 52 threads with locking surface 48 to lock housing 12 with holder 22. A length of umbilical cord 16, which includes arteries, veins, etc. is clamped with surgical clamps (not shown) or the like. The length of umbilical cord 16 should be adequate for sampling, such as, for example, 8-30 centimeters.

As shown in FIG.6, an end 60 of the length of umbilical cord 16 is placed in housing 12. It is not required that the entire length of umbilical cord 16 be disposed within cavity 14 of

housing 12. Cord blood 13 is caused to flow into cavity 14 and pool in funnel 16. Cord blood 13, due to the fluid flow path communicating between housing 12 and female luer connector 30, and gravity, flows to needle hub 54 and needle cannula 56.

Evacuated tube 28 is inserted within cavity 27 of holder 22 to establish fluid communication between female luer connector 30 and evacuated tube 28 for collecting cord blood 13 via second end 26. Rubber stopper 58 is driven into cavity 27 such that needle cannula 56 punctures rubber stopper 58. Needle cannula 56 is disposed in the evacuated space of tube 28. As discussed, cord blood 13 is drawn into the evacuated space of tube 28. The collection of cord blood 13 is facilitated by the fluid communication established via the needless sealing engagement of male luer connector 20 and female luer connector 30.

Housing 12 is drained of the remaining cord blood 13, filling of tube 28 and/or acquisition of a sufficient sample. Tube 28 is removed from needle cannula 56 to discontinue cord blood collection, as shown in FIG. 7. The components of fluid collection apparatus 10 may be disposed and the cord blood sample may be analyzed, etc.

In an alternate embodiment, as shown in FIGS. 8 – 10, housing 12 is maintained in an upright orientation by a base 66 that is disposed with housing 12 and configured for support thereof. Base 66 can be assembled with housing 12 or integrally formed therewith. Referring to FIG. 8 base 66 is adapted to fit around the body of housing 12 and holds housing 12 upright by supporting flange portions 67 that extend radially from housing top edge 70. In an illustrative embodiment, support top edge 72 defines a top opening 74 adapted for accepting the body of housing 12. Bottom edge 76 of base 66 provides a level support for standing housing 12 on a surface, such as, for example, a tabletop, work surface, etc.

Base 66 is configured to enclose holder 22 and has a height sufficient to support housing 12 and holder 22 installed therewith. Alternatively, a base may be provided with sufficient height to support housing 12, holder 22 and an evacuated tube (not shown) installed in holder 22 above a flat surface. It is envisioned that base 66 can be embodied as a hollow cylinder having a top opening diameter greater than housing 12 outside diameter but less than the radial extension of flange portions 67. The hollow cylinder can have a circular cross section or it may be formed as a rectangular cylinder, truncated cone or any such structure having a top opening capable of accepting housing 12 and holder 22 together and supporting them in an upright orientation. It is

further envisioned that base 66 may include other configurations, such as, for example, solid portions, side wall openings, columns, etc.

Base 66 may be formed from a suitable inexpensive manufacturing material, such as, for example polyethylene, polypropylene, nylon, PVC or the like. Base 66 may be fabricated using a number of alternative common manufacturing process. For example, it is envisioned that a cylindrical base 66 can be inexpensively manufactured using an extrusion process or alternatively may be injection molded. An injection molded base 66 may also include a sidewall having a number of cut-outs (not shown) to reduce material usage, provided sufficient structural integrity is maintained to support a blood filled housing and holder with an evacuated tube installed therein, for example.

Base 66 may be designed with an inside diameter or cross sectional shape adapted to match the outside diameter or cross sectional shape of housing for a press-fit therewith. A press –fit base 66 can eliminate the need for a flange or similar support features on housing 12 against which to abut support top edge 72. Alternatively, attachment structure may be provided on the inside surface of base 66 and/or outside surface of housing 12 to secure housing 12 within base 66. For example, threads, snap arms, annular grove/ring features and the like can be provided on adjacent surfaces of housing 12 and base 66 for attaching one to the other. In another alternative embodiment, an adhesive material or epoxy may be used to secure base 66 to housing 12.

In another embodiment, as shown in FIG. 9, a base 80, similar to that described above, is provided to support housing 12 in an upright orientation. Base 80 is adapted to fit around bottom portion 83 of housing 12 and holds housing 12 upright by supporting housing bottom edge 82 on step 86. Base 80 includes a top edge 85 that defines a top opening adapted for accepting the body of housing 12. Bottom edge 90 of base 80 provides a level support base for standing base 80 on a flat surface.

Base 80 includes an inside surface having at least one rib 88 extending inward therefrom. Rib 88 extends from bottom edge 90 along a partial height of base 80 and terminates at a height defining a step 86 for supporting housing 12. Step 86 can be horizontal or angled to match an inclined bottom surface of housing 12, for example.

Base 80 has a height sufficient to support housing 12 and holder 22 installed therewith. Alternatively, base 80 may be provided with sufficient height to support housing 12, holder 22 and an evacuated tube (not shown) installed in holder 22 above a flat surface. It is envisioned that base 80 has a circular cross section or it may be formed as a rectangular cylinder, truncated cone or any such structure having a top opening capable of accepting bottom portion 83 of housing 12 and holder 22 together and supporting housing 12 and holder 22 in an upright orientation.

Alternatively, base 80 may be designed with an inside diameter or cross sectional shape adapted to match the outside diameter or cross sectional shape of bottom portion 83 of housing 12 for a press-fit therewith. A press–fit base 80 can eliminate the need for ribs having a step or similar support features. Attachment structure, adhesive, etc. may be provided to secure housing 12 within base 80.

In another alternate embodiment, as shown in FIG. 10, the base, similar to that described, includes a wall extension 92 that extends from bottom portion 83 of housing 12. Bottom edge 94 of wall extension 92 provides a level support base for standing housing 12 on a flat surface.

Wall extension 92 has a height sufficient to support housing 12 and holder 22 installed therewith. Alternatively, a wall extension 92 may be provided with sufficient height to support housing 12, holder 22 and an evacuated tube (not shown) installed in holder 22 above a flat surface. Wall extensions 92 are separated by a pluraltiy of cut-outs 98. Cut-outs 98 may have alternative configurations and dimensions according to the particular strength and material usage requirements for a particular application. The base may include one or a plurality of cut-outs 98.

The fluid collection apparatus according to the present disclosure may also include a removable cap 100 adapted to cover the top opening of housing 12 and provide a fluid seal with the top portion of housing 12. Referring to FIG. 11A, a removable cap 100 includes a sealing portion 104 capable of fitting against the housing 12 to provide a fluid seal therebetween. In the illustrative embodiment, the diameter of sealing portion 104 corresponds to inside diameter of housing 12 to provide a press fit therebetween. Sealing portion 104 can optionally include an elastomeric o-ring or the like to provide a more robust fluid seal. Attachment of removable cap 100 to housing 12 can alternatively be provided by mating threads in cap and housing, snap

arms, annular ring/groove or bump feature 106 (FIG. 11B) with a corresponding recess (not shown) in housing 12 or the like. A gripping portion such as finger grip 102 can be provided to facilitate easy removal of cap 100 from housing 12. Cap 100 can be formed as a separate component or can be monolithically formed with housing 12, for example, using at least one living hinge.

In another embodiment of the fluid collection apparatus, a holder 114, similar to that described, includes a removable cap 106, similar to that described above, as shown in FIG. 12. Cap 106 is provided to cover housing 12 and provide a fluid seal therebetween. Holder 114 includes an orifice 108 adapted for mounting a cannula 56. A cannula 56 extends from orifice 108 toward the outside of housing 12 when cap 106 is installed on housing 12. Cannula 56 is in fluid communication through orifice 108 with a tube 110 having a port 112 opening inside housing 12 when cap 106 is installed to housing 12. Tube 110 extends toward the bottom of housing 12 to submerge port 112 in fluid collected therein.

Holder 114 is adapted to receive an evacuated fluid collection tube 130. Sidewall 116 of holder 114 extends into the cavity defined by housing 12 forming a cylinder having an open top and a bottom wall 118. Orifice 108 is disposed through bottom wall 118 such that cannula 56 extends into the tubular cavity defined by holder 114. Tube 110 extends from bottom wall 118 into the cavity defined by housing 12.

Housing 12 has a tapered bottom surface 120 defining a well portion 122 for collecting fluid. Port 112 is disposed in well portion 122 for improved fluid collection. Housing 12 can also include sidewall extensions 124 extending below tapered bottom walls such that housing is capable of being stood upright on a flat surface. Alternatively, a separate support 66 (FIG. 8) or base 80 (FIG. 9) can be used to support housing 12 on a flat surface.

Cannula 56 and tube 110 are optionally provided as a prefabricated sub-assembly such as cannula 56 and hub 54 assembly used in fluid collection holder described hereinbefore (FIGS 4-7). Orifice 108 is dimensioned to provide an interference fit with hub 54 whereby hub supports cannula 56 and tube 110 therein. Cannula 56 can optionally include a rubber valve disposed thereon as known in the art.

Cap 106 covers top opening of housing 12 and provides a fluid seal with the top portion of housing 12. A sealing portion 104 capable of fitting against the housing 12 provides a fluid

seal therebetween. In the illustrative embodiment, the diameter of sealing portion 104 corresponds to inside diameter of housing 12 to provide a press fit therebetween.

An optional re-sealable fluid vent (not shown) can be provided in cap 108 or housing 12 to facilitate aspiration of fluid into an evacuated tube by allowing air under atmospheric pressure into housing.

To operate the illustrative embodiment shown in FIG. 12, a cap 106 is first removed if one is installed to housing, for example, for shipping and packaging purposes. A fluid sample, such as an umbilical cord section having blood draining therefrom is placed in the cavity of housing 12. Cap 106 is then installed to housing 12 such that port 108 is immersed in fluid to be collected. An evacuated tube 130 having a rubber stopper 132 is placed over cannula 56 and pushed down onto cannula 56 such that cannula 56 punctures rubber stopper 132 and provides a fluid passageway from the cavity of housing 12 into the evacuated fluid collection tube 130. Vacuum pressure in evacuated tube 130 causes fluid to flow upward through port 112, tube 110, cannula 56 and into evacuated tube 130. When a sufficient fluid sample is collected into fluid collection tube 130, fluid collection tube 130 is removed from cannula 56. In at least one embodiment, rubber valve (not shown) self-seals around needle cannula 56 and rubber stopper 132 self-seals collection tube 130.

The cavity formed by sidewall 116 is deep enough to contain the entire length of cannula 56 to thereby protect users from accidental needle-stick injuries. In a particular embodiment, a closable fluid vent (not shown) is also provided in cap 106 and/or housing 12. In operation the closable vent is opened to allow air to flow into cavity of housing 12 under atmospheric pressure while a collection tube 130 is installed on cannula 56 to aid aspiration of fluid into evacuated tube.

Clinicians are thereby provided with a method and apparatus to efficiently and safely collect fluid samples such as umbilical cord blood while maintaining collected fluid, waste fluid and tissue in safely sealed containers. The fluid collection apparatus according to the embodiment shown in FIG. 12 also provides protection from exposure to needle stick hazards.

Turning now to FIGS. 13A – 13D, another embodiment of the present disclosure provides a fluid collection apparatus having a housing 138 that defines chambers 140, 142 and a passageway 144 therebetween. A housing, such as, for example, first chamber 140 is adapted for

receiving a fluid sample such as an umbilical cord section having blood draining therefrom, and a holder, such as, for example, second chamber 142 is adapted for collecting fluid therefrom. A sloped bottom surface 146 directs fluid from first chamber 140 to second chamber 142 through passageway 144. Housing 138 includes an extension 145 defining a base portion having a bottom edge 147 adapted for standing on a surface. Housing 138 may include one or a plurality of chambers.

Housing 138 includes a sidewall 139 and bottom surface 146 that define a cavity with first and second chambers 140, 142. Second chamber 142 is adapted to receive a collection tube holder 150. Collection tube holder 150 has a body portion 152 defining a tubular cavity 154 for receiving an evacuated tube. Tubular cavity 154 has a top opening 156 and a bottom wall 158 with a hub 160 extending through bottom wall 158. A port 164 extends from hub 160 into second chamber 142. A cannula 162 extends from hub 160 toward top opening 156. Cannula 162 is in fluid communication with port 164. Cannula 162 optionally includes a rubber valve providing a fluid seal between cannula 162 and hub 160.

A removable cap 170 is adapted to cover first and second chamber 140, 142 to prevent fluid leakage therefrom (FIG. 13D). Cap 170 includes a first chamber cover 172, a second chamber cover 174 and a hinge 176 therebetween such that first chamber cover 172 and second chamber cover 174 can be opened and closed independently of each other. Cap 170 includes at least one finger grip 178 extending from the first and/or second chamber cover 172, 174. A cap extension 180 extends into and seals a slot that forms passageway 144. Cap 170 can be made from rubber or suitable plastic or elastomeric material as known in the art, such as for example, polypropylene, nylon, polyethylene or the like. It is envisioned that cap 170 can be formed as a separate component or can be formed monolithically with housing 138 using at least one living hinge therebetween, for example.

In operation, the apparatus shown in FIGS 13A-13D to collect umbilical cord blood is used by first placing a section of umbilical cord into first chamber 140. Collection tube holder can be installed in second chamber 142 before or after fluid is allowed to drain into second chamber. When fluid has drained into second chamber 142, port 164 of collection tube holder 150 extends into a pool of fluid. An evacuated tube 190 (FIG. 13C) having a rubber stopper 192 is placed over cannula 162 and pushed down onto cannula 162 to puncture rubber stopper

192 and provides a fluid passageway from second chamber 140 into the evacuated fluid collection tube 190. Vacuum pressure in evacuated tube 190 causes fluid to flow upward through port 164 and cannula 162 and into evacuated tube 190. When a sufficient fluid sample is collected into fluid collection tube 190, fluid collection tube 190 is removed from cannula 162. A rubber valve (not shown) may self seal around needle cannula 162 and rubber stopper 132 may self seal collection tube 130.

Clinicians using the embodiment shown in FIGS. 13A-13D are thereby provided with an alternative method and apparatus according to the present disclosure for efficiently and safely collecting fluid samples such as umbilical cord blood while maintaining collected fluid, waste fluid and tissue in safely sealed containers which also provide protection from exposure to needle stick hazards.

Although various embodiments of the present disclosure are described in terms of a two chamber apparatus, persons having ordinary skill in the art should appreciate that any number of chambers may be combined to provide a multi-chamber fluid collection apparatus according to the present disclosure.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting but merely as exemplification of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.